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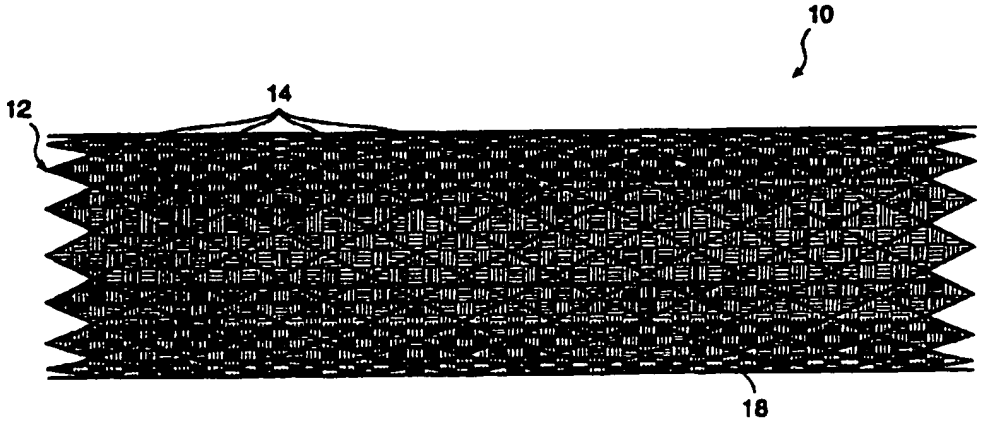

(57) Abstract

This invention is a population of radially expansible stents (14) having substantially uniform characteristics and a method for producing a population of stents with predetermined, uniform thermal and mechanical properties. The process includes deforming the stents into a hollow tube having a desired diameter, and heating the stents sufficiently to homogenize the microstructure of the alloy, thereby increasing stents' ductility to about 40 %-50 % strain. After heating, the stents are shape-set at a desired diameter at an A_f temperature below body temperature. The high ductility and homogenized microstructure increases the fatigue life and improves the uniformity of the population of stents. In addition, the method of the present invention allows the A_f temperature to be shifted up or down during processing, providing more precise control of the final A_f temperature.

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A POPULATION OF INTRALUMINAL PROSTHESIS HAVING UNIFORM CHARACTERISTICS AND A PROCESS FOR MAKING THE SAME

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. Provisional Patent Application Serial No. 60/020,963, filed on June 25, 1996, the full disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to radially expansible intraluminal prostheses, such as grafts, stents, stent-grafts and the like. More particularly, the invention provides a population of radially expansible tubular prostheses having substantially uniform and predictable characteristics, and a process for forming the population of prostheses.

Luminal prostheses, commonly known as grafts, stents or stent-grafts, are tubular-shaped devices which function to hold open a segment of a blood vessel or other anatomical lumen. These stent-grafts, stents and grafts are provided for a variety of medical purposes. For example, stents can be placed in various body lumens, such as blood vessels and the ureter, urethra, biliary tract and gastrointestinal tract, for maintaining patency. Stents are particularly suitable for supporting dissections in the arterial tissue that may occur during, for example, balloon angioplasty procedures. Such dissections can occlude an artery and prevent the flood of blood therethrough. In addition, stents may be used to support grafts to form a stent-graft for lining or replacing

weakened blood vessels, such as in aortic aneurysm repair procedures (e.g., aneurysms occurring in the abdominal aorta, usually beginning below the renal arteries and often extending distally into one or both of the iliac arteries). Stent-grafts (hereinafter referred to as stents) typically refer to structures formed by attaching a separate liner or "graft", which may comprise a woven polyester, such as Dacron™, or a plastically expansible material, such as PTFE, to a cylindrical frame or "stent".

Many types of stents are typically manufactured from tubular materials, such as tubing made of stainless steel, or a nickel titanium alloy (i.e., Nitinol™), that when formed into a stent can be made to expand radially. Such stents have the mechanical hoop strength to maintain lumen patency and/or mechanically augment the luminal wall strength. Malleable expandable stents are caused to yield from their compressed state by internal force to fill the lumen or the vessel. Radially self-expanding stents are typically made from a material that is capable of being deformed by an applied stress, and then springing back or recovering to its original unstressed shape. Shape memory alloys that have a memory of an expanded shape are particularly advantageous in stents because these alloys are capable of being stretched or otherwise deformed into a smaller diameter or unstable configuration and endoluminally introduced into the vasculature through a small diameter access device, such as an introducing catheter. Typically, the shape memory alloy will revert, or attempt to revert, from its unstable configuration to its original, stable configuration upon the application of heat, or upon the removal of a restraint, e.g., the introducing catheter.

Among metallic alloys, such as Nitinol™, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state. The transformation between states may be caused by a change in temperature, sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy can be deformed from its original

configuration to a new configuration when cooled below the temperature which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s, the deformed object will begin to return to its original configuration (A_f being the temperature at which the reversion is complete). A further description of this phenomenon can be found in U.S. Patent No. 4,935,068 to Duerig, the complete disclosure of which is incorporated herein by reference.

Under certain conditions, shape memory alloys are known to display pseudoelasticity or superelasticity, typically referred to as stress-induced martensite. When a shape memory alloy is exhibiting stress-induced martensite, it is stressed at a temperature above M_s (so that the austenitic stage is initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress). The alloy first deforms elastically, and then at a critical stress, begins to transform by the formation of a stress-induced martensite. If the temperature is above A_s, the martensite is unstable and transforms back to austenite upon release of the constraint. A further description of stress-induced martensite stent medical devices can be found in U.S. Patent No. 4,665,906 to Jervis, the complete disclosure which is incorporated herein by reference.

To manufacture stents and stent-grafts, cylindrically spaced slots or openings are usually cut into the walls of hollow tubes, typically by laser cutting or photoetching methods. Alternatively, the stents may be formed from a flat sheet, which is deformed into a generally cylindrical configuration after the slots have been cut through by laser cutting, photoetching, electron discharge machining (EDM), stamping or the like. This relatively new procedure is described in co-pending, commonly assigned, U.S. Patent Application Serial No. 08/593,515, filed January 30, 1996, the complete disclosure of which is incorporated herein

by reference. The slots or openings in the hollow tubes are then polished to remove slag particles and other debris from the rough surfaces of the stents.

Once the stent has been formed, the slotted tube is expanded and the shape memory alloy is processed so that the stent has certain mechanical and thermal properties suitable for implantation and expansion within a body lumen. An important parameter in manufacturing stents is the ability to process a large population of such stents that have substantially uniform, predictable characteristics. This is particularly important in the manufacture of self-expanding stents because some stent properties may not be discovered until the stent is actually deployed within the patient's vasculature. A stent that does not exhibit the desired behavior or properties within the patient's vasculature may result in a failed deployment, or later stent migration, which can injure the patient or cause trauma or other complications during the surgical procedure.

One important characteristic or property exhibited by stents is the radial force applied by the stent against the luminal wall after the stent has transformed into the austenitic state and expanded to its final enlarged diameter within the body lumen. Radial force is the mechanism in which the stent or stent-graft anchors into the vessel to hold open the vessel and to prevent migration of the stent due to loads applied to the stent, such as blood flowing through the stent or the expansion and contraction of the blood vessel from the patient's heart beat. A relatively low radial force exerted against the luminal wall will allow the stent to migrate along the body lumen whereas a relatively large radial force may potentially damage the luminal wall, e.g., by contributing to aneurysmal growth.

Thermoelastic stents will usually be formed to have a transformation temperature A_f, (i.e., the temperature at which the stent will completely revert back to the austenite state within the body lumen) below body temperature so that the stent automatically expands when released at the target site within the body lumen. It is often difficult, however,

to control the transformation temperatures of shape memory alloys with accuracy, as they are usually extremely composition-sensitive. In addition, the A_f temperature of stents may often shift during in-catheter thermal cycling conditions. Since the radial force exerted by the stent is related to the A_f, the upward shift in A_f will decrease the radial force. In addition, an upward shift in A_f could cause the A_f to go above body temperature so that the stent does not transform into the austenite state after implantation.

Another important property of stents is their fatigue life or their ability to withstand loads within a body lumen over a long period of years. When a stent is subjected to repeated stress cycles, fatigue may cause the stent to fail. These repeated stress cycles can be caused by a variety of loads within a body lumen, such as blood flow, the continuous expansion and contraction of the vessel, etc. These loads may eventually cause the stent to completely fail or to lose its grip on the luminal wall, causing potential injury to the patient and often requiring another surgical procedure to remove the failed stent and deploy a second stent at the same portion of the diseased vessel or to effect surgical repair of the vessel.

For these and other reasons, it would be desirable to provide methods and apparatus for manufacturing a population of elastic intraluminal prostheses which exhibit substantially uniform and predictable characteristics upon deployment within the patient's vasculature and thereafter. These methods and apparatus should be capable of producing a relatively large number of stents having a long fatigue life and a consistent, predictable phase transition temperature A_f that remains stable during constrained storage conditions and/or endoluminal delivery into a patient's vasculature. It would be further desirable to produce a population of stents capable of exerting a substantially uniform radial force against a luminal wall after the stents have been expanded within the body lumen to decrease migration of the stent and to minimize injury to the body lumen.

2. Description of the Background Art

The properties of nickel/titanium shape memory alloys are described by T.W. Duerig and A.R. Pelton in an article entitled "TI-NI Shape Memory Allows", a reprint from Materials Properties Handbook, Titanium Alloys, ASM International 1994, and by C.M. Jackson, H.J. Wagner and R.J. Wasilewski in an article entitled "55-Nitinol-The Alloy with a Memory: Its Physical Metallurgy, Properties and Applications", Technology Utilization Office, National Aeronautics and Space Administration (1972).

Surgical devices incorporating elastic materials, such as shape memory alloys, are described in U.S. Patent Nos. 5,254,130, 5,486,183, 5,345,937, 4,512,338 and 4,601,283, European Patent Application No. 0 688 545 A1, and Canadian Patent Application No. 2,079,944. U.S. Patent No. 4,935,068 teaches some of the fundamental properties of shape memory alloys. U.S. Patent No. 4,665,906 to Jervis describes medical devices, including catheters and cannulas, which make use of the pseudoelastic or stress-induced martensitic (SIM) properties of certain shape memory alloys. U.S. Patent No. 4,310,354 to Fountain describes a method of blending alloys of differing transformation temperatures by powder metallurgy to control the transformation temperature A_f of the resulting alloy. U.S. Patent No. 4,631,094 to Simpson discloses a process of increasing the transformation hysteresis of a nickel/titanium based shape memory alloy. U.S. Patent No. 4,067,752 to Brook describes a process for increasing the reversibility of a shape memory alloy.

SUMMARY OF THE INVENTION

The present invention provides a population of elastic or pseudo-elastic intraluminal tubular prostheses having substantially uniform and predictable characteristics and a method for producing the population of intraluminal prostheses. The present invention is particularly useful for producing a population of endovascular stents, grafts or stent-grafts configured for minimally invasive delivery and

implantation within a body vessel of a patient. The present invention is advantageous because the exact mechanical and thermal properties exhibited by elastic prostheses may not be known until the prostheses have been deployed in the patient. Thus, providing a plurality of intraluminal prostheses having consistent, predictable characteristics allows for optimal performance before, during and after implantation into the body vessel, and it minimizes prosthesis failure or other consequences associated with inadequate and unexpected performance of these devices.

The population of elastic or pseudo-elastic intraluminal prostheses according to the present invention usually comprises at least 2 prostheses, preferably at least 10 prostheses and more preferably greater than 100 prostheses. Each prothesis includes a hollow radially expansible tube sized for delivery through an anatomical lumen and having first and second open ends and an inner lumen therebetween. The tube is preferably perforated or slotted to facilitate radial expansion. The hollow tube comprises a shape memory alloy material, such as Nitinol™, that is capable of being deformed into a small diameter by an applied stress, and then springing back or recovering to a larger diameter when the stress is removed. The shape memory alloy may display thermoelastic behavior so that the stent transforms to the larger diameter by the application of heat or it may exhibit pseudoelastic or superelastic behavior, in which the stent returns to the larger diameter upon the removal of a constraint. In the former case, the shape memory alloy will preferably return to the larger diameter at an A_f temperature below body temperature or below 37°C. In the latter case, the shape memory allow will usually display stress-induced martensite at body temperature such that the stent returns to the larger diameter upon removal of a restraining device, such as an introducing catheter.

In a first aspect of the invention, the population of intraluminal prostheses are configured such that, when each stent is located within a body vessel in a radially expanded configuration, the stent will exert a radial force against the

vessel wall that is sufficient to securely anchor the prosthesis to the wall and to hold open the body vessel without causing substantial injury to the vessel. The radial force exerted by each prosthesis within the population will be substantially equivalent and will typically depend on the individual vessel and the function of the prostheses. Usually, the radial force will be sufficient to radially distend the vessel wall between about 1 to 20% of the inner diameter of the vessel and preferably about 5 to 10% of the inner vessel diameter. This radial force is typically large enough to prevent migration of the prosthesis from the target site due to blood flowing therethrough, expansion and contraction of the blood vessel during the continuous pulse of the patient and other loads applied to the prosthesis. In addition, the radial force applied by the prosthesis is small enough to minimize injury to the vessel wall, such as aneurysmal growth, abnormal vessel distension and the like.

In a second aspect of the invention, the population of prostheses exhibit a substantially equivalent final A_f temperature within a body lumen. Usually, the A_f temperature of each of the prostheses will fall within about 5°C of a desired temperature and preferably within about 2°C of the desired temperature. Since the radial force exerted by each prosthesis is generally related to the A_f temperature, accurately controlling this temperature will facilitate control of the radial force. In addition, the desired A_f temperature will typically be substantially below body temperature (i.e., 37°C) to effectively ensure that each of the prostheses will return to the desired expanded configuration within the patient's body. Usually, the desired A_f temperature is between about -20°C and 35°C, preferably about 25°C to 35°C and more preferably about 28°C to 30°C.

In a preferred configuration, the population of prostheses are configured such that the A_f temperature remains substantially stable when each prosthesis is in a constrained storage condition and/or during endoluminal introduction into the patient's body through, for example, an access device and an introducing catheter. Thermal and mechanical loads applied

to a stent while the stent is in a constrained storage condition and during deployment and implantation often cause the A_f temperature to increase prior to transformation to the expanded state (often referred to as the free recovery A_f shift). The present invention minimizes the free recovery A_f shift. Usually, the A_f temperature of each prosthesis will shift by a factor of less than about 10% of the desired temperature and preferably less than about 5% of the desired temperature.

In a third aspect of the invention, the population of intraluminal prostheses are formed such that each prosthesis, when located within a body lumen in the expanded configuration, has a fatigue life of at least 5 years, preferably greater than 10 years. As used herein, fatigue life generally refers to the length of time a stent or graft may be subjected to repeated stress cycles without failing. Stent failure can include the loss of sufficient hoop strength to maintain lumen patency or hold the prosthesis in place within the lumen, the tearing, severing or breaking of a portion of the stent, such as an axial or circumferential strut or beam element within the stent, and other breakdowns in the tubular body that result in the inability of the stent to perform a desired function within a body lumen. Repeated stress cycles are typically caused by a variety of loads within a body lumen, such as blood flow, expansion and contraction of the vessel, etc. Increasing the fatigue life of the stents minimizes second and third operations that may be necessary or desirable to remove and replace a stent that has completely failed or migrated to a different location within the vasculature. In addition, increasing the stent's lifetime will minimize exposure of the patient to the consequences of failed or migrated stents, such as fluid leakage, aneurysm rupture, etc.

The method for forming a population of intraluminal prostheses according to the present invention involves deforming a hollow radially expansible tube comprising a shape memory alloy into a desired diameter, and applying sufficient heat to the tube to substantially homogenize the alloy. The

homogenization step increases the ductility of the stent (usually on the order of about 40 to 50% strain) and removes dislocations from the alloy, which increases the fatigue life of the stents and improves the uniformity of the stents that are produced by the process. In addition, the high ductility of the stents may contribute to reduction of the residual martensite after a load-unload cycle, e.g., during in-catheter thermal cycling, thereby minimizing the free recovery A_f shift of the stent during constrained storage conditions and endoluminal delivery into the patient's vasculature.

The hollow tube is expanded or otherwise deformed to a second or final diameter either before or after the heating or homogenization step. Usually, the tube is expanded after heating because the high ductility of the alloy will facilitate the expansion process. In some stent configurations, the strain necessary to expand or deform the stent into the final diameter is low enough to allow such expansion or deformation without increasing the ductility of the stent (i.e., a low strain/expansion ratio). In these configurations, the stent will be heated sufficiently to homogenize the alloy microstructure after the stent has been deformed into the final desired configuration.

In one embodiment, the homogenization step comprises a heat annealing step prior to deformation of the stent. The heat annealing step includes heating each stent sufficiently to increase the ductility of the stents to about 40% to 50% strain. Although the specific heat treatment will vary depending on the shape memory material, the final desired diameter and other factors, the stents are preferably subjected to a heat treatment at about 550°C to 650°C for about 1/2 to 2 hours. After this annealing heat treatment, each stent is usually expanded to a final diameter or to an intermediate diameter. In the latter case, the stent will be subjected to additional heating and expansion steps until the stent is at the final desired diameter.

The stents are then preferably shape set at the final diameter by subjecting each tube to a solution treating process that involves heating each tube at a relatively high

temperature for a short period of time, and then quenching the heated tubes with a cooled fluid. The solution treating step also removes dislocations that may have formed during expansion of the stent. Usually, the stents will be heated at a temperature of about 700°C to 1000°C for about 1 minute to one hour. Preferably, the heat treatment will last about 5 to 30 minutes, with the exact timing depending on the initial A_f temperature of the stent and the desired target A_f temperature among other factors. The solution treating step will also decrease the A_f temperature of the stent, usually the A_f will be reduced to about -30°C to 50°C, preferably below body temperature, and more preferably between about -20°C and 10°C.

In another embodiment, the stents are deformed into the final desired configuration, and then subjected to the solution treating step described above. In this embodiment, the stents are not subjected to a heat annealing step, and the homogenization step is accomplished by solution treating the deformed stents. The solution treating step removes dislocations within the stent to substantially homogenize the alloy and thereby increase its ductility. In addition, the solution treating step decreases the A_f temperature of the stent.

After the stents have been deformed and homogenized (i.e., through solution treating, heat annealing or both) each stent is preferably subjected to an aging heat treatment that produce precipitates within the microstructure, thereby increasing the superelasticity of the stent. The superelasticity of the stent is increased so that, after the tube has been deformed by an applied stress (e.g., thermally or by compressing the stent for introduction through a catheter), the shape memory material will return to the second diameter when the stress is removed. In addition, the aging heat treatment raises the A_f temperature of the stent to the desired point, usually about 0°C to 36°C, preferably about 25°C to 35°C and more preferably about 28°C to 32°C. Accordingly, the length of the aging step will depend on the initial A_f temperature, the final desired A_f temperature and other factors.

Another advantage of the inventive process is that the A_f temperature of the stent can be shifted up or down during processing. Thus, if one of the parameters of the manufacturing process (e.g., the composition of the shape memory allow, the oven temperature, etc.) is inaccurate, the A_f temperature of the stent can be corrected before the process is complete. This allows more precise control of the final A_f temperature and increases the stability of the stent's A_f temperature.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side view of a stent-graft which is exemplary of the population of radially expansible tubular prostheses according to the present invention;

Fig. 2 illustrates an exemplary bifurcated endovascular prosthesis having a relatively rigid expanded Y-connector portion, axially flexible branch and trunk portions, and sealing/anchoring cuffs;

Figs. 3A-3C illustrate an exemplary endoluminal prosthetic structure in which the frame is supported by a helical coil of expansible diamond shaped elements, for use in the flexible portions of the prosthesis of Fig. 2;

Figs. 4A-4C illustrate alternate flexible prosthetic structures in which the liner is supported by a plurality of cylindrical segments;

Fig. 5A illustrates an endoluminal prosthetic structure in which a liner is supported by a plurality of self-expanding loops, and in which serpentine malleable connectors extend between adjacent loops;

Figs. 5B-5G show alternative connector structures and connector attachment mechanisms for use in the prosthesis of Fig. 5A;

Fig. 6 is a flow diagram illustrating a method for producing the population of stents of Fig. 1 according to the present invention;

Figs. 7A-7C illustrate an exemplary mandrel for uniformly expanding a stent or stent-graft according to the present invention;

Fig. 8 is a flow diagram illustrating another method for producing a population of stents according to the present invention; and

Figs. 9A and 9B illustrate an alternative mandrel for uniformly expanding a stent or stent-graft.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a population of radially expansible intraluminal tubular prostheses, particularly grafts, stents or stent-grafts, having substantially uniform characteristics. The present invention also provides a method for processing the population of luminal prostheses. As discussed in greater detail below, the characteristics that can be accurately and uniformly controlled by the present invention include the fatigue life of the luminal prostheses within a body lumen, the A_f temperature of the prostheses, the stability of the A_f temperature during constrained storage conditions and/or intraluminal delivery to the target body lumen, the final diameter of the expanded protheses, the radial force applied by the prostheses against a luminal wall, and other mechanical and thermal properties discussed in detail below.

The population of intraluminal prostheses of the present invention will include more than one prosthesis and will usually exceed at least ten prostheses. Preferably, the population will include at least 50 protheses and more preferably greater than 100 protheses. A particular advantage of the present invention is that the prostheses within the population will have substantially consistent, predictable characteristics, allowing for optimal performance before, during and after implantation into the body vessel. In addition, this minimizes the potential for prosthesis failure or other consequences associated with inadequate and unexpected performance of these devices.

The present invention will be extremely useful in producing stents or stent-grafts for minimally invasive placement within the vasculature for the treatment of diseases, such as aneurysms, stenoses, and the like. The population of stents will be capable of being compressed into a narrow-diameter configuration to facilitate introduction into the body lumen, typically during surgical cutdown or percutaneous introduction procedures. Accordingly, the stents will have a sufficient amount of elasticity to allow the stent to be compressed into the narrow-diameter configuration without causing significant deformation of the shape memory material. Usually, the stents exhibit greater than 4% elastic deformation and preferably greater than 8% elastic deformation. Exemplary delivery catheters and methods for placement of the prostheses of the present invention are more fully described in co-pending U.S. Patent Application Serial No. 08/475,200 (Attorney Docket No. 16380-11-3), the complete disclosure of which is incorporated herein by reference.

The stents each include a hollow radially expansible tube sized for delivery through an anatomical lumen and having first and second open ends and an inner lumen therebetween. The tubes are formed from a resilient shape memory alloy material that is capable of being deformed by an applied stress, and then recovering to its original unstressed shape. The alloy material will usually exhibit thermoelastic behavior so that the stents will transform to the original unstressed state upon the application of heat (i.e., an A_f temperature below body temperature). The prostheses may also exhibit stress-induced martensite, in which the martensite state is unstable and the prosthesis transforms back to the original state when a constraint has been moved (i.e., when the stent is released from an introducing catheter within a body lumen).

The material for the shape memory alloy will be selected according to the characteristics desired of the population of prostheses. Preferably, the shape memory alloy will comprise a nickel titanium based alloy (i.e., Nitinol™), which may include additional elements which affect the characteristics of the prosthesis, such as the temperature at

which the shape transformation occurs. For example, the alloy may incorporate additional metallic elements, such as copper, cobalt, vanadium, chromium, iron or the like.

As mentioned previously, the preferred embodiment of the present invention utilizes shape memory alloys that transform into a larger diameter configuration at a critical temperature (A_f temperature). Preferably, the A_f temperature of the prostheses is substantially below body temperature (body temperature being about 37°C) so that the prostheses will automatically expand upon release from the introducing device within the body lumen. It is often difficult to control the A_f temperature of shape memory alloys with accuracy, as they are usually extremely composition-sensitive, and sensitive to the initial amount of cold working in the material. The population of prostheses of the present invention have a substantially equivalent, accurate A_f temperature, usually having an A_f temperature that falls within 5°C of the desired A_f temperature and preferably within 2°C of the desired A_f temperature. The A_f temperature not only determines when the stents will expand, but it also contributes to the radial force exerted by the stents (discussed below). Accordingly, providing a consistent A_f temperature will cause the prostheses to exert a substantially equivalent radial force against the vessel wall. Usually, the desired A_f temperature is about -20°C to 35°C, preferably about 25°C to 35°C, and more preferably about 28°C to 30°C. However, this temperature may vary depending on the desired radial force, the design of the stent and other factors, such as the storage temperature of the stent in the constrained configuration. For example, a lower A_f temperature may increase the stiffness of the stent, allowing the stent to be manufactured with less mass for a given amount of stress in the vasculature.

The A_f temperature of the population of prostheses is substantially stable during constrained storage and/or delivery through the introducing device. Typically, the thermal and mechanical loads placed upon the stents during constrained storage and/or endoluminal delivery into the

patient's vasculature shifts the A_f temperature of a stent to a higher temperature (often referred to as free recovery A_f shift). This increase in A_f temperature will generally decrease the radial force exerted by the stent and could cause failure of the stent if the A_f temperature exceeds the body temperature. Applicant has found that the amount of free recovery A_f shift is usually caused by the stress condition of the shape memory material which is a function of the geometry of the stent, the degree of compression into the catheter, the environmental storage temperature, the A_f temperature and the material processing techniques. The material processing technique of the present invention minimizes the shift in A_f temperature so that it does not exceed the body temperature and so that the radial force exerted by the stent is not significantly decreased during catheter delivery. Preferably, the A_f temperature of each stent manufactured by the present invention will shift by a factor of less than 10% and more preferably less than 5% during constrained storage and when the stents are delivered into the vasculature with an introducing catheter.

The population of stents of the present invention will have a relatively long fatigue life in the expanded configuration within a body lumen of the patient. As used herein, fatigue life generally refers to the length of time a stent or graft may be subjected to repeated stress cycles without failing. Stent failure can include the loss of sufficient hoop strength to maintain lumen patency or hold the prosthesis in place within the lumen, the tearing, severing or breaking of a portion of the stent, such as an axial or circumferential strut or beam element within the stent, and other breakdowns in the tubular body that result in the inability of the stent to perform its function within a body lumen. These repeated stress cycles can be caused by a variety of loads within a body lumen, such as blood flow, the continuous expansion and contraction of the vessel, etc. Applicant has determined that the fatigue life of the stent is generally related to the stress in the shape memory material as well as the fatigue resistant properties of the material.

The stress can typically be varied through geometric design change and the fatigue properties of the material can be varied through material processing techniques (discussed below).

The fatigue life of the prostheses of the present invention has been tested by simulating the loads applied to a typical stent within a body lumen and applying these loads to the stents for a large number of stress cycles. The population of prostheses are usually capable of withstanding at least 40 million stress cycles (about 1 year), preferably at least 200 million stress cycles (about 5 years) and more preferably greater than 400 million stress cycles (about 10 years). Thus, the prostheses will usually be capable of withstanding about at least five years of service within a body lumen of the patient and preferably greater than 10 years. The long fatigue life of these stents minimizes potential injury that could be caused by failure of a stent within a disease vessel. In addition, it prevents additional surgical procedures that are often necessary or desirable to remove the failed stent and deploy a second stent at the same portion of the diseased vessel.

When a stent is located within a body lumen, such as a blood vessel, in an expanded configuration, its final desired diameter is typically larger than the inner diameter of the vessel to provide an interference fit. Thus, the stent will exert a radially directed force against the luminal wall to hold open the body lumen. The radial force is the mechanism in which the stent anchors into the vessel to prevent migration due to fluid flow and other loads within the vessel. Radial force also contributes to the sealing capabilities of a composite stent-graft along with the circumferential conformance. Although it is important to have a strong enough radial force to anchor the stent to the vessel, too large a radial force can potentially injure the vessel wall. For example, a large radial force exerted against a blood vessel can potentially contribute to aneurysmal growth or abnormal distention of the vessel. Applicant has found that the radial force exerted by the stent

on the vessel is typically a function of the stent geometry, the amount of compression into the constrained, smaller diameter configuration, the A_f temperature, the material processing techniques and the temperature of the blood or other fluids within the body lumen.

The population of stents of the present invention have a substantially uniform and predictable radial force when they are in an expanded configuration within a body lumen. The exact amount of desired radial force will depend upon a variety of factors, such as the flow rate within the vessel, the strength of the vessel wall, the function of the stent within the vessel, etc. Usually, the stents will each exert a radial force against the vessel wall that is sufficient to securely anchor the prosthesis to the wall and to hold open the body vessel without causing substantial injury to the vessel. The exact radial force exerted by the stents will typically depend on the individual vessel and the desired function of the stents. Usually, the radial force will be sufficient to radially distend the vessel wall between about 1 to 20% of the inner diameter of the vessel and preferably about 5 to 10% of the inner vessel diameter. This radial force is sufficient to prevent migration of the stent from the target site due to blood flowing therethrough, expansion and contraction of the blood vessel during the continuous pulse of the patient and other loads applied to the stent. In addition, the radial force applied by the stent is small enough to minimize injury to the vessel wall, such as aneurysmal growth, leakage and the like.

Figure 1 illustrates a representative intravascular stent-graft structure from the population of stent structures produced according to the present invention. It should be understood, however, that although a particular stent-graft structure is described below and shown in Figure 1, the present invention is not intended to be limited to this structure. That is, the method of the present invention can be utilized to manufacture a variety of grafts, stents or stent-grafts commonly used in this art. For example, representative conventional stent structures made from

metallic tubular materials that are currently marketed as implants for coronary, peripheral, biliary and other vessels include the Palmaz-Schatz™ balloon expandable stent, manufactured by Johnson and Johnson Interventional Systems, Co. and the Memotherm™ stent manufactured by Angiomed, a division of C.R. Bard, Inc.. Other stents or grafts that can be processed according to the present invention include a coiled structure, such as that described in U.S. Patent No. 5,476,505 to Limon, an open mesh or weave stent structure formed of helically wound and/or braided strands or filaments of a resilient material, described in U.S. Patent No. 5,201,757 to Heyn, a filament knitted into a mesh cylinder, described in U.S. Patent No. 5,234,457 to Andersen, a tubular structure having diamond shaped openings, described in U.S. Patent Nos. 5,242,399 to Lau or U.S. Patent No. 5,382,261 to Palmaz, Z-shaped stents as described in U.S. Patent No. 5,282,824 to Gianturco, continuous wire stents, such as the one described in U.S. Patent No. 5,292,331 to Boneau, stents formed of filaments that are wound into spiral or other suitable shapes as described in U.S. Patent No. 5,314,471 to Fountaine, a continuous helix of zig-zag wire and loops described in U.S. Patent No. 5,405,377 to Cragg and a variety of other types of stents that can be suitably manufactured from a shape memory alloy.

As shown in Fig. 1, stent-graft structure 10 includes a perforate tubular frame 12 which includes a plurality of independent (non-connected or connected) ring frames 14. The tubular frame 12 supports an inner liner 18. Optionally, an outer liner (not shown) is disposed over the ring frames 14, either instead of inner liner 18, or in combination therewith. Inner liner 18 is usually formed from a polymeric sheet material and is typically sutured to frames 14. A wide variety of alternative liner/frame attachment mechanisms are available, including adhesive bonding, heat welding, ultrasonic welding, and the like. Where inner and outer liners are used, the ring frames may be sandwiched between the liners and held in place by attaching the liners to each other. In a typical embodiment, stent-graft structure

to Muller, the complete disclosure of which is incorporated herein by reference.

Alternatively, the stents may be manufactured from a substantially planar sheet of alloy material, which is stamped, laser cut, photoetched, electro-discharge machined (EDM) or the like to form slots or openings therein. The slotted sheet is then deformed into a tubular configuration by locating a tapered mandrel near the center of the planar sheet, and axially translating the planar sheet over the tapered mandrel. The edges of the planar sheet are folded downward as the sheet is moved over the mandrel to form a tubular configuration. A complete description of this process can be found in co-pending, commonly assigned U.S. Patent Application Serial No. 08/593,515, filed January 30, 1996, the complete disclosure of which has already been incorporated herein by reference. This type of stent may be particularly advantageous with the present invention because the stent has a low strain/expansion ratio. Usually, this ratio is low enough such that the stent can be deformed into the final desired configuration without subjecting the stent to a heat annealing step, as discussed in detail below.

The slots and cut edges of the stents will then be polished to remove slag particles of the debris from the rough surfaces of the stents. One such method involves a process called electropolishing, which is a bulk process for removing the sharp corners and edges as well as polishing the wall surfaces and cut surfaces of metallic stents. This technology comprises a reverse electroplating process in which stents are preferably supported by a conductive wire and submerged in a caustic liquid solution, such as a mixture of phosphoric and sulfuric acid. A cathode is also submerged into the electrolytic solution so that an electric potential can be established between the cathode and the anode. The electric potential removes metallic material from the stent to thereby polish the wall surfaces and round the edges of the stent. Other methods include chemical etching, mechanical deburring with an abrasive media.

Once the stents have been formed and the slots have been suitably polished, the slotted tubes are expanded or otherwise deformed and the shape memory materials are processed and shape set to the final stent configuration having the desired dimensions and A_f temperature. According to the present invention, the stents are deformed into a hollow radially expansible tube comprising a shape memory alloy and having a desired diameter, and subjected to a heating step sufficient to substantially homogenize the alloy. The stents may be heated prior to, or after, they are deformed depending on the geometry of the stent among other factors. The heating or homogenization step substantially increases the ductility of the stent (usually on the order of about 40 to 50% strain) and removes dislocations from the alloy, which increases the fatigue life of the stents and improves the uniformity of the stents that are produced by the process. In addition, the high ductility of the stents (i.e., less dislocations in the material) may contribute to a reduction in the residual martensite after a load-unload cycle, e.g., during in-catheter thermal cycling, thereby minimizing the free recovery A_f shift of the stent during constrained storage conditions and endoluminal delivery into the patient's vasculature.

Referring to Fig. 6, a first embodiment of the method of the present invention will now be described. In this embodiment, the stents are generally heated prior to expansion or deformation to increase the ductility of the shape memory alloy. Accordingly, the stents are first subjected to a heat annealing step, which usually involves placing the stents in a heat source, such as an oven, salt pot or the like, and heating the stents sufficiently to increase their ductility and to relieve cold working in the microstructure or remove dislocations (i.e., soften the stents to reduce their strain/expansion ratio). As used herein, ductility generally refers to the strain to failure of the material. In a specific configuration, the annealing step includes heating each stent sufficiently to increase the ductility of the stents to about 40% to 50% strain. Although

the specific heat treatment will vary depending on the shape memory material, the final desired diameter and other factors, the stents are preferably subjected to a heat treatment at about 550°C to 650°C for about 1/2 to 2 hours.

After the heat annealing treatment, the stents are still at the initial, as manufactured, diameter, which is substantially less than the final desired diameter. Accordingly, each stent is usually expanded to a final diameter or to an intermediate diameter. In the latter case, the stent will be subjected to additional heating and expansion steps until the stent is at the final desired diameter. In a preferred configuration, the stents are each placed on a fixture, such as a mandrel, and the mandrels are radially expanded to thereby radially expand the stents to the final desired diameter. Alternatively, the stents may be placed on a tapered mandrel that has an increasing diameter from one end to the other. In this embodiment, the stents will be moved axially relative to the tapered mandrel so that the stents' diameter increases with the mandrels' diameter. Depending on the stent design, the high ductility of the stents may allow them to be continuously expanded to the final diameter in one shot at room temperature.

Figs. 7A-7C illustrate an exemplary mandrel 150 for indexing repeated patterns or shapes around the circumference of a prosthesis. The mandrel 150 comprises tubular body 152 having a diameter substantially equal to the desired final diameter of the prosthesis. The body 152 includes a plurality of holes 154 arranged in rows and uniformly spaced around the circumference of the body 152. Mandrel 150 will also include a plurality of pins 155 (see Fig. 7C) that fit within holes 154 to index or hold repeated patterns of the prosthesis 170 together during expansion so that the prosthesis 170 will expand substantially uniformly. In a preferred configuration, the prosthesis 170 will have diamond shaped openings 156 in the tubular configuration, as shown in Figs. 1 and 7C. The holes 154 are spaced such that two of the pins 155 engage either end 158, 160 of the diamond shaped openings 156 (see Fig. 7C) to prevent these openings 156 from expanding non-

uniformly as the prosthesis is moved axially relative to the mandrel 150.

Figs. 9A and 9B illustrate an alternative mandrel 180 having a plurality of depressions 182 arranged in rows and spaced uniformly around the circumference of the mandrel 180. As shown in Fig. 9A, depressions 180 are sized to fit between the ends 184, 186 of adjacent diamond shaped openings 188 of a prosthesis to prevent openings 188 from expanding non-uniformly.

It should be understood that the stents may be expanded to the final diameter prior to the high temperature heat treatment. Alternatively, the stents may be expanded in steps and heated between each expansion step. It is preferred, however, to subject the stents to a high temperature heat treatment first because this increases their ductility and facilitates the expansion process (i.e., allows for a greater expansion before stent failure).

Once the stents have been expanded or otherwise deformed to the final diameter, they are each shape set at this diameter such that, after the stent has been deformed by an applied stress, the shape memory material will return to the final diameter when the stress is removed. As discussed above, the stents will preferably return to the final diameter at an A_f temperature below body temperature. According to the present invention, the stents are subjected to a solution treating process, in which the tube is heated sufficiently to increase the A_f temperature to the desired point. In addition the solution treating process removes any dislocations that may have been added to the stent during expansion.

In an exemplary configuration, the solution treating process involves heating each stent at a relatively high temperature for a short period of time, and then quenching the heated tubes with a cooled fluid. Usually, the stents will be heated at a temperature of about 700°C to 1000°C for about 1 minute to one hour. Preferably, the heat treatment will last about 5 to 30 minutes, with the exact timing depending on the initial A_f temperature of the stent and the desired final A_f temperature among other factors. The solution treating step

will also decrease the A_f temperature of the stent, usually to about -30°C to 36°C and preferably about -10°C to 10°C.

After the solution treating process has been completed, the elasticity of the stents will be further increased so that each stent can be deformed by an applied stress to a smaller diameter than the initial, as manufactured, diameter for endoluminal delivery into the patient's vasculature. An increased elasticity will also facilitate the subsequent return to the final diameter upon removal of the applied stress. In a preferred embodiment, the stents are subjected to an aging heat treatment to produce fine precipitates within the microstructure, thereby increasing the superelasticity of the stent. In stents that comprise a nickel titanium alloy, the aging heat treatment will separate nickel precipitates to increase the elasticity of the alloy. Usually, the stents will be heated at a low temperature of about 300°C to 550°C, preferably about 325°C to 400°C for about 1 min to about 2 hours. The aging heat treatment raises the A_f temperature of the stent to the desired point, usually about 0°C to 50°C, preferably about 25°C to 35°C and more preferably about 28°C to 32°C. Accordingly, the length of the aging step will depend on the initial A_f temperature, the final desired A_f temperature and other factors.

In some stent configurations, the strain necessary to expand or deform the population of stents into the final diameter is low enough to allow such expansion or deformation without increasing the ductility of the stent (e.g., stents having a low strain/expansion ratio). In these configurations, the stents will usually be deformed into the final configuration without heat annealing the stent, as shown in the flow diagram of Fig. 3. The stents are then subjected to solution treating (as discussed above) to substantially homogenize the alloy microstructure, thereby increasing the stents' ductility. Stents having a strain/expansion ratio low enough to eliminate the heat annealing step are described in co-pending application Serial No. 08/593,515, which has already been incorporated herein by reference. As mentioned

previously, these stents are manufactured from a substantially pattern of alloy material formed into a pattern. The patterned sheet is folded over a tapered mandrel into a tubular configuration by locating a tapered mandrel near the center of the planar sheet, and axially translating the planar sheet over the tapered mandrel. Applicant has found that these stents may be deformed into the tubular, expanded configuration without heating the stents prior to such deformation and without creating significant stress within the stent.

In an alternate method, the stents are subjected to a cold working/aging process to shape set the final diameter and A_f temperature of the shape memory material. Cold working a shape memory alloy generally involves introducing a high density of random dislocations or imperfections into the atomic structure. The dislocations impede the mobility of twin boundaries so that the material has a substantially low ductility and a low superelasticity. A subsequent heat treatment aging process rearranges the dislocations into cells of relatively dislocation-free areas within which the martensite twins can be mobile but surrounded by dislocation networks, the material exhibits high superelasticity and ductility. This provides a structure with relatively high superelasticity (6-10% strain), relatively high stiffness and good mechanical cycling stability. A more detailed description of cold working alloys can be found in "Ni-Ti Based Shaped Memory Alloys", K.N. Merton, ENGINEERING ASPECTS OF SHAPE MEMORY ALLOYS, pages 21-35 (1990), the complete disclosure of which is incorporated herein by reference.

The cold work/aging process of the present invention will usually involve heating and expanding the stent in incremental steps to both shape set the tubular prosthesis and to raise the A_f temperature to the desired level. The temperature for these steps will usually range from about 300°C to 550°C. Generally, higher temperatures within this range will result in aggressive shape setting and, therefore, will not require as many incremental steps in order to reach the final desired diameter as lower temperatures within this

range. Aging the stent at higher temperatures, however, generally results in a lower A_f shift rate per minute than aging at lower temperatures. Thus, the specific process parameters will depend on the initial and final A_f temperatures, the initial and final diameters of the stent and other factors.

One cold work/aging method involves expanding the "as cut" stent to an intermediate diameter between the initial diameter and the final austenitic stent diameter at room temperature with a tapered mandrel, for example. The mandrel and stent are then placed in a heat source at a temperature in the range of about 400 - 550°C for a period of time sufficient to achieve full shape set at the intermediate diameter. The stent is then taken out of the heat source and quenched in water to set the shape. The stent may then be placed over another intermediate diameter fixture or directly onto a final diameter fixture. The expanded fixture and stent are placed in the heat source with similar conditions, e.g. about 400-550°C, to set the shape of the stent at the final diameter. At this point, the heated stent is measured for free recovery A_f. The heat steps are adjusted to produce A_f at or below the specifications. If the A_f is below the specifications, the stent can be placed into the heat source of the same temperature for a given amount of time to raise the A_f to the desired level. The A_f temperature generally increases as a function of time when the temperature is constant. If the A_f is above the specifications, the stent may be placed into a high temperature heat source (e.g., usually about 525°C to 1000°C and preferably about 525°C to 550°C) for a relative short period of time, e.g., about 1 to 5 minutes. This additional heat process will reduce the A_f temperature of the stent.

This method involves expansion of the stent in incremental steps governed by the stress level developed at each step. The stress developed at each step has two components, where the sum of those components should not exceed the ultimate strength of the material. The first component (expansion stress) is the stress developed by

expansion to a particular diameter from the stress-free state. The second component (thermal stress) is the stress developed due to the constrained heating when the expanded stent on the fixture is placed into the heat source. The stress in the material uniformly increases with an increase in temperature until a peak is reached at approximately 200 - 300°C. The stress rate is approximately 6 MPa/C°. If the sum of the expansion stress and the thermal stress exceed the ultimate strength of the material, the stent may break when placed in the heat source.

Another method of cold working/aging is a one step method where the slotted tube is placed in a fixture, which is either encapsulated by a hot chamber or develops heat internally. The fixture is expanded in the hot state until the stent reaches the final diameter. The expansion rate, temperature and time are controlled to result in a dimensionally correct stent with the proper A_f temperature. The basic concept of this method is to place the stent in a low stress environment where the expansion and shape setting can occur dynamically, instead of in discrete increments like the multi-step expansion method described above. This process is relatively benign to the stent as long as the expansion rates are controlled.

Radially expansible prostheses typically undergo a mechanical shrinkage when returning to the austenitic state due to incomplete recovery of the shape memory alloy. This mechanical shrinkage causes the stents to have a smaller diameter than the desired diameter within the body lumen, which may affect the ability of the stent to hold open the body lumen, and may decrease the radial force applied to the luminal wall. The level of the incomplete recovery may be dependent on a variety of factors, such as the stress level in the material, the amount of compression into the introducing catheter, the environmental exposure temperature and the material processing techniques. Applicant has found that increasing the base diameter of the stent to compensate for this shrinkage tends to increase the stress level of the stent and, therefore, is not an adequate solution to the problem of

mechanical shrinkage. The cold working processing techniques described above minimize the mechanical shrinkage of the stent during delivery into the patient. Typically, the population of prostheses will undergo a mechanical shrinkage of less than about 10% of the final desired diameter in the expanded configuration and preferably about 5% of the final diameter.

WHAT IS CLAIMED IS:

1. A population of intraluminal prostheses having substantially uniform and predictable characteristics, each prosthesis comprising:

a hollow radially expansible tube sized for delivery through an anatomical lumen and having first and second open ends and an inner lumen therebetween, the tube comprising a material that is capable of being deformed between a first configuration having a first diameter, and a second configuration having a second diameter larger than the first diameter; and

wherein the hollow tube of each of the population of prostheses, when located within a body vessel in the second configuration, exerts a radial force against the vessel wall sufficient to anchor the hollow tube to the wall and to hold open the body vessel without causing substantial injury to the vessel wall.

2. The population of intraluminal prostheses of claim 1 wherein the material is a shape memory material that exhibits thermoelastic behavior such that each tube will return to the second configuration at a temperature below body temperature.

3. The population of intraluminal prostheses of claim 1 wherein the material of each tube is a shape memory material that exhibits pseudoelastic behavior such that the tube will return to the second configuration upon removal of a restraint.

4. The population of intraluminal prostheses of claim 1 wherein the hollow tube of each prostheses, when located within a body vessel in the second configuration, exerts a radial force against the vessel wall sufficient to radially distend the vessel wall between about 1% to 20% of the diameter of the vessel.

5. The population of intraluminal prostheses of claim 1 wherein each tube, when positioned within a body vessel in the second configuration, exerts a radial force against the vessel wall sufficient to radially distend the vessel wall between about 5% to 10% of the inner diameter of the vessel.

6. The population of intraluminal prostheses of claim 1 wherein the population includes at least 10 prostheses.

7. The population of intraluminal prostheses of claim 1 wherein the population includes at least 100 prostheses.

8. The population of intraluminal prostheses of claim 1 wherein the body vessel is a blood vessel.

9. The population of intraluminal prostheses of claim 1 wherein the shape memory alloy comprises a nickel titanium alloy.

10) A population of intraluminal prostheses having substantially uniform and predictable characteristics, each prosthesis comprising:

a hollow radially expansible tube comprising an elastic, shape memory material that is capable of being deformed between a first configuration having a first diameter, and a second configuration having a second diameter larger than the first diameter;

wherein the shape memory material has been formed to return to the second configuration at an A_f temperature below body temperature; and

wherein the A_f temperature of each of the population of intraluminal prostheses falls within 5°C of a desired A_f temperature such that each of the prostheses, when located within a body vessel, exerts a substantially equivalent radial force against the vessel wall.

11. The population of intraluminal prostheses of claim 10 wherein the A_f temperature of each of the population of intraluminal prostheses falls within 2°C of a desired A_f temperature.

12. The population of intraluminal prostheses of claim 10 wherein the desired A_f temperature is between about 28°C and 32°C.

13. The population of intraluminal prostheses of claim 10 wherein the A_f temperature of each prosthesis remains substantially stable when the prosthesis is in a constrained storage condition at a diameter less than the second diameter.

14. The population of intraluminal prostheses of claim 10 wherein each of the population of intraluminal prostheses is configured such that, when the prosthesis is in a constrained storage condition at a diameter less than the second diameter, the free recovery A_f temperature shifts by a factor of less than 10%.

15. The population of intraluminal prostheses of claim 10 wherein each of the population of intraluminal prostheses is configured such that, when the prosthesis is in a constrained storage condition at a diameter less than the second diameter, the free recovery A_f temperature shifts by a factor of less than 5%.

16. A population of intraluminal prostheses having substantially uniform and predictable characteristics, each prosthesis comprising:

a hollow radially expansible tube comprising a shape memory material capable of being deformed between a first configuration having a first diameter, and a second configuration having a second diameter larger than the first diameter; and

wherein each of the population of prostheses, when located within a body vessel in the second configuration, will

be capable of withstanding at least 40 million physiological stress cycles without failing.

17. The population of intraluminal prostheses of claim 16 wherein each of the population of prostheses will be capable of withstanding at least 200 million physiological stress cycles without failing.

18. The population of intraluminal prostheses of claim 16 wherein each of the population of prostheses will be capable of withstanding at least 400 million physiological stress cycles without failing.

19. The population of intraluminal prostheses of claim 16 wherein at least a portion of the stress is caused by fluid flow through the body lumen.

20. The population of intraluminal prostheses of claim 16 wherein the body lumen is a blood vessel, at least a portion of the stress being caused by expansion and contraction of the blood vessel.

21. The population of intraluminal prostheses of claim 16 wherein each of the prostheses, when located within a body lumen in the second configuration, has a fatigue life of at least 5 years.

22. The population of intraluminal prostheses of claim 16 wherein each of the prostheses, when located within a body lumen in the second configuration, has a fatigue life of greater than 10 years.

23. A process for forming an intraluminal prosthesis comprising:

providing a radially expansible hollow tube having a first diameter and comprising a shape memory material;

applying sufficient heat to the hollow tube to substantially homogenize the shape memory material; and

shape setting the tube at the first diameter such that, after the tube has been deformed by an applied stress, the shape memory material will return to the first diameter when the stress is removed.

24. The method of claim 23 further comprising radially expanding the tube from a second diameter to the first diameter.

25. The method of claim 24 wherein the applying heat step comprises subjecting the prosthesis to a heat annealing step before the radially expanding step to relieve cold working in the shape memory alloy and to substantially increase the ductility of the prosthesis.

26. The method of claim 25 wherein the annealing step increases the ductility of the shape memory material to at least 40%.

27. The method of claim 23 further comprising deforming a substantially planar element into a tube having the first diameter.

28. The method of claim 27 wherein the deforming step is carried out without heating the planar element.

29. The process of claim 23 wherein the applying heat step comprises subjecting the prothesis to a solution treating step that increases the ductility of the shape memory material to at least 40%.

30. The process of claim 23 wherein the applying heat step comprises subjecting the prothesis to a solution treating step that increases the ductility of the shape memory material to at least 50%.

31. The process of claim 25 wherein the ductility of the shape memory material is sufficiently increased to

allow substantially continuous expansion of the tube from the second diameter to the first diameter.

32. The process of claim 23 wherein the shape memory alloy comprises a nickel titanium alloy.

33. The process of claim 29 wherein the solution treating step includes heating the tube to a temperature of about 700 to 1000°C for about 5 to 30 minutes.

34. The process of claim 33 wherein the shape setting set comprises quenching the tube with a cooled fluid after the heating step.

35. The process of claim 25 wherein the heat annealing step comprises heating the tube at a temperature of about 550 to 650°C for about 1/2 to 2 hours.

36. The process of claim 23 wherein the shape memory material exhibits thermoelastic behavior, the process including the treating the shape memory material so that the tube will return to the first diameter at an A_f temperature below body temperature.

37. The process of claim 23 further comprising shifting the A_f temperature of the tube during the process.

38. The process of claim 29 wherein the A_f temperature of the shape memory material is decreased to a temperature of about -20°C to 10°C during the solution treating step.

39. The process of claim 23 further comprising, after the shape setting step, further increasing the elasticity of the tube such that the tube can be deformed by an applied stress to a third diameter less than the second diameter, the tube being capable of transforming to the first diameter upon removal of the applied stress.

40. The process of claim 39 wherein the elasticity of the tube is increased to at least 8%.

41. The process of claim 39 wherein the elasticity increasing step is carried out by creating fine precipitates from the alloy microstructure.

42. The process of claim 41 wherein the creating precipitates step comprises subjecting the stent to an aging heat treatment to the tube such that the A_f temperature of the prosthesis is increased to about 20°C to 35°C.

43. A process for forming a population of intraluminal prostheses having substantially uniform and predictable characteristics, the process comprising:

providing a plurality of radially expansible hollow tubes having a desired diameter and comprising a shape memory material; and

applying sufficient heat to each tube to substantially homogenize the shape memory material such that, after each tube has been deformed by an applied stress, the shape memory material will return to the desired diameter at an A_f temperature within 2.5°C of a desired temperature, the desired temperature being substantially equivalent for each of the population of prostheses.

44. The method of claim 43 further comprising radially expanding each tube from an initial diameter to the desired diameter.

45. The method of claim 44 wherein the applying heat step comprises heat annealing each prosthesis before the radially expanding step to relieve cold working in the shape memory alloy and to substantially increase the ductility of the prostheses.

46. The method of claim 43 further comprising deforming one or more substantially planar elements into a plurality of tubes having the desired diameter.

47. The process of claim 46 wherein the applying heat step comprises subjecting the prostheses to a solution treating step that substantially increases the ductility of the shape memory material.

48. The process of claim 43 further comprising treating the hollow tubes such that each tube of the population of prostheses, when located within a body vessel at the desired diameter, exerts a substantially equivalent, predetermined radial force against the vessel wall.

49. The process of claim 48 wherein the radial force exerted by each tube is sufficient to radially distend the vessel wall between about 5 to 10% of the diameter of the vessel.

50. The process of claim 43 further comprising treating each of the hollow tubes such that, during constrained storage of each of the prostheses, the A_f temperature shifts by a factor of less than 10%.

51. The process of claim 43 further comprising treating each of the hollow tubes such that, when positioned within a body vessel at the desired diameter, the tube has a fatigue life of at least 10 years.

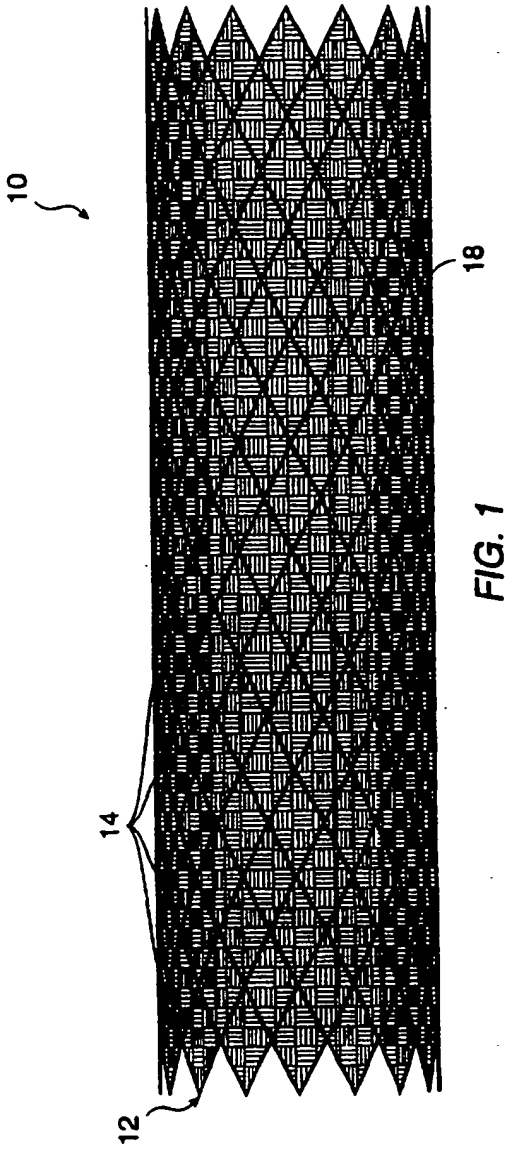

FIG. 1

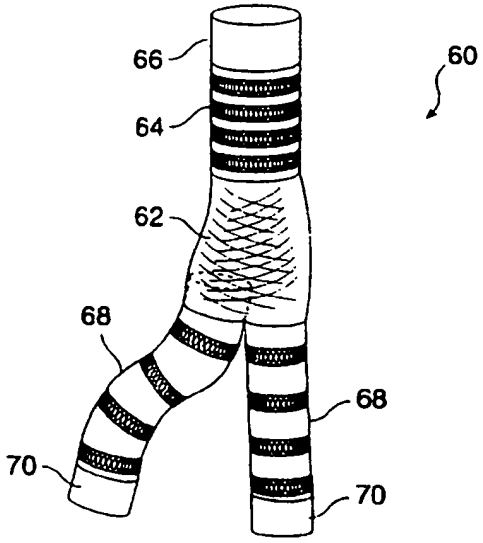

FIG. 2

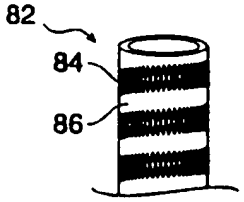

FIG. 3A

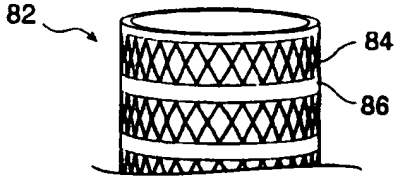

FIG. 3B

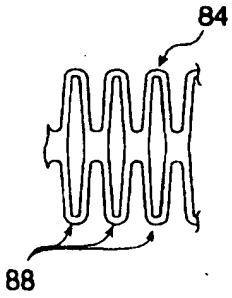

FIG. 3C

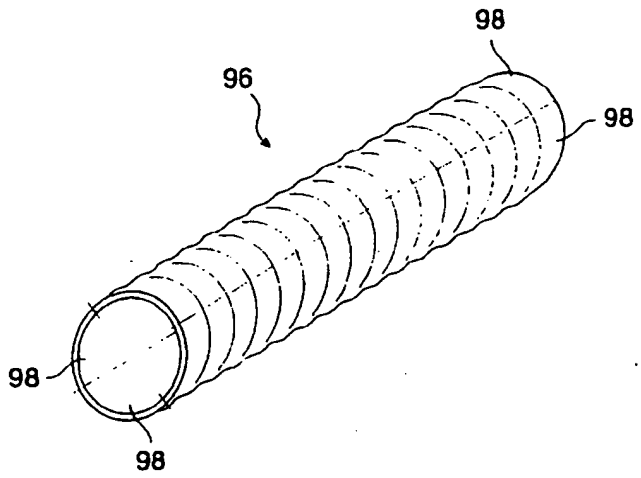

FIG. 4A

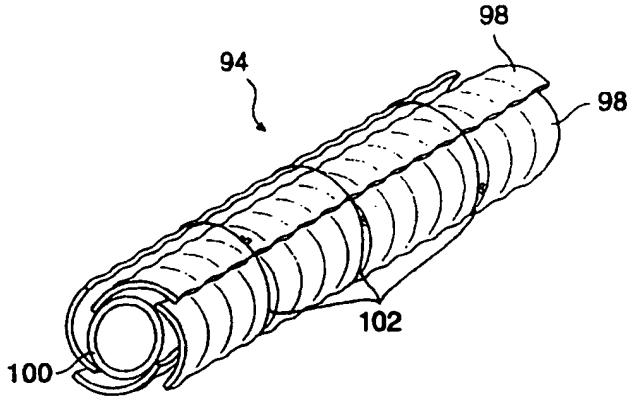

FIG. 4B

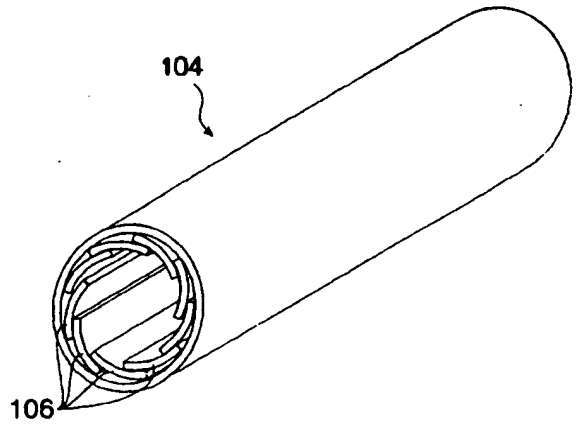

FIG. 4C

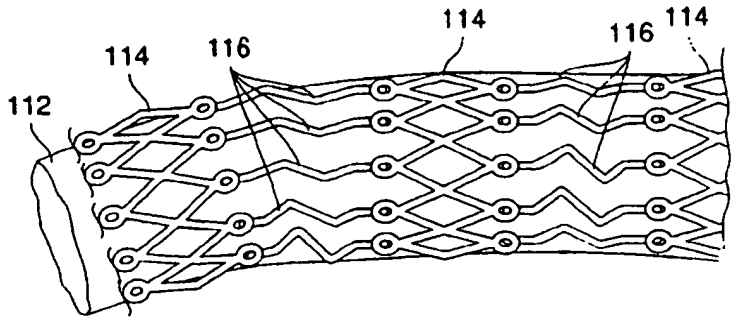

FIG. 5A

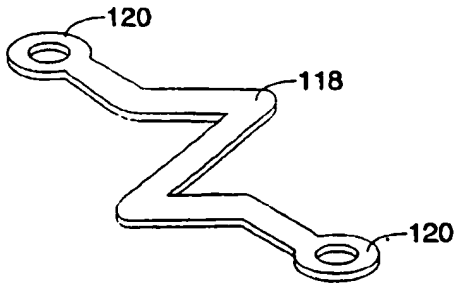

FIG. 5B

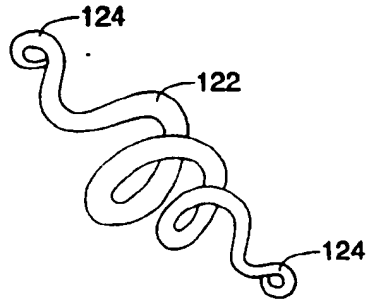

FIG. 5C

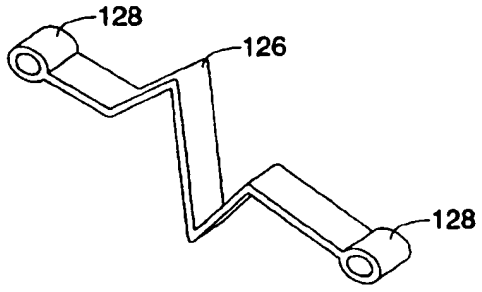

FIG. 5D

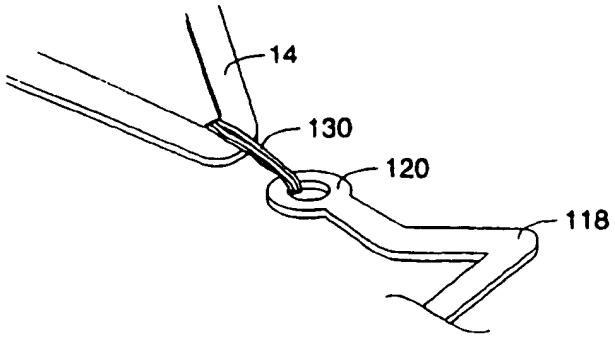

FIG. 5E

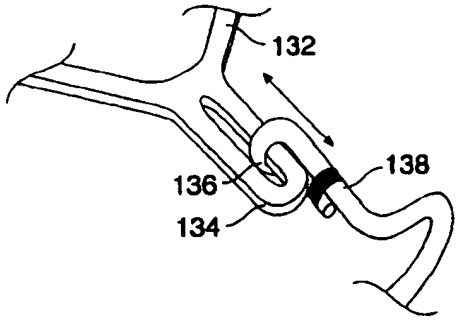

FIG. 5F

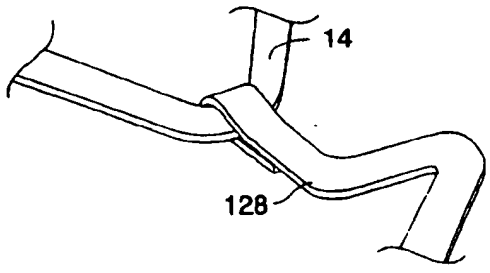

FIG. 5G

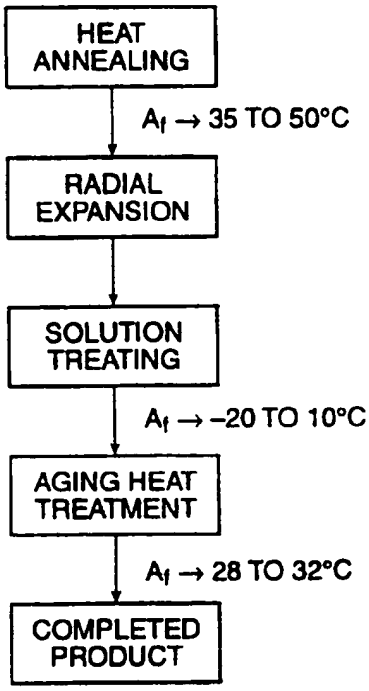

FIG. 6

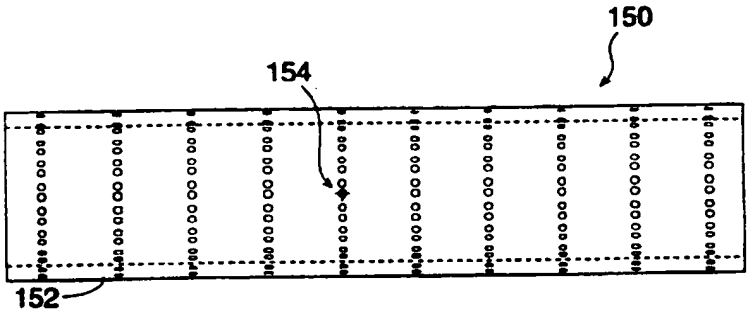

FIG. 7A

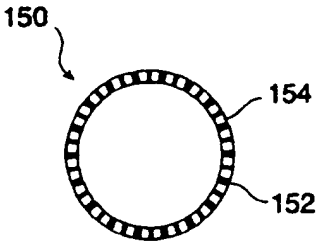

FIG. 7B

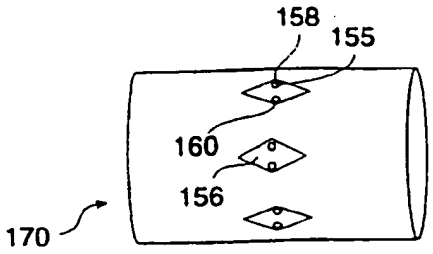

FIG. 7C

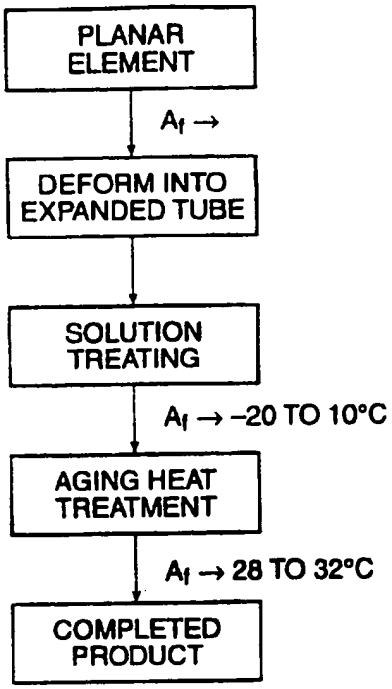

FIG. 8

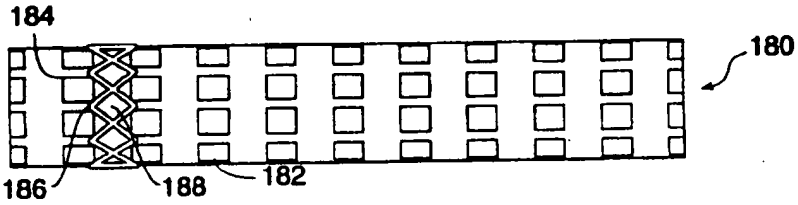

FIG. 9A

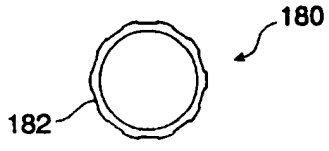

FIG. 9B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/10924

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61F 2/06
US CL. :623/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/36; 606/194. 195. 198; 623/1. 11. 12

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,449,373 A (PINCHASIK et al.) 12 September 1995, figures.	1-51
Y	US 5,405,377 A (CRAGG) 11 April 1995, col. 2, lines 50-59.	1-51
X,P	US 5,545,210 A (HESS et al.) 13 August 1996, entire document.	1-51
A	US 5,507,771 A (GIANTURCO) 16 April 1996.	1-51

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 02 AUGUST 1997	Date of mailing of the international search report 05 SEP 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer DEBRA S. BRITTINGHAM Telephone No. (703) 308-3401

Form PCT/ISA/210 (second sheet)(July 1992)*